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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,472	04/16/2004	Michelle L. Monje	STAN-303	1490

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EXAMINER	
DUTT, ADITI	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
12/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,472	MONJE ET AL.	
	Examiner	Art Unit	
	Aditi Dutt	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *7,8,11,12 and 17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9,10 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/9/04,8/8/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

1. The amendments of 15 June 2007 and 5 October 2007 have been entered in full. Claims 18-20 have been withdrawn by Applicant.

Election/Restrictions

2. Applicant's election of Group I, claims 1-17 drawn to a method of protecting an individual from a loss of neurogenesis, in the reply filed on 15 June 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Applicant's election of species as "disease" for a pathological condition set forth in Claim 13 in the response dated 5 October 2007 to the Office communication dated 10 September 2007, is acknowledged. However, Applicant was requested to elect a specific pathological condition from the species as listed in claims 9, 10, 12, 16 and 17. It was notified that claim 13 is a generic claim and was mistakenly included in the claims listing the species (see lines 3-5 of Office communication dated 10 September 2007). Applicant's election of the species "disease" from claim 13 (other species in the claim being 'surgical intervention' and 'injury'), changes the requirement of species election as set forth in the previous Office Actions. To continue timely prosecution, Examiner withdraws the

previous species requirement of specific "pathological conditions". The current election of "disease" and "non-steroidal anti-inflammatory agent" as the species for pathological conditions and anti-inflammatory agent will be considered in the instant application.

4. **The requirement is still deemed proper and is therefore made FINAL.**

5. Claims 7, 8, 11, 12, 16 and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 15 June 2007.

6. Claims 1-6, 9-10, and 13-15 are under consideration in the instant application.

Claim Rejections - 35 USC § 112-Second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-6, 9-10, 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1 is rejected, as being vague and indefinite, because the clinical status of the 'individual' is not defined. It is not clear whether the individual is any normal individual of any age group, or an individual belonging to a particular risk

category, or an individual having neuroinflammation or at the onset of neuroinflammation. Appropriate clarification is requested.

9. The term "protecting" in claim 1 is a relative term which renders the claim indefinite. The term "protecting" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "protecting" does not clearly convey the meaning in context with the present claims. Examiner is not sure whether it means 'preventing', 'reducing' or 'stopping' an individual from a loss of neurogenesis capacity.

10. Claims 2-6, 9-10 and 13-15 are rejected as they depend from an indefinite claim.

Double Patenting

Statutory

11. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

12. A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

13. Claims 1-6, 9-10 and 13-15, are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-6, 10-11 and 14-16 of co-pending U.S. Application No. 11/473,196. This is a double patenting rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 1-5, 14, are rejected under 35 U.S.C. 102(b) as clearly anticipated by Tada et al. (Neurosurgery 41: 209-219, 1997 – online publication 1-19 pages).

15. The claims recite a method of protecting an individual from loss of neurogenesis resulting from inflammation and microbial activation, comprising

contacting the individual with anti-inflammatory agent, wherein the loss in neurogenesis capacity is reduced (claims 1, 2), wherein the neurogenesis is associated with the central nervous system (claim 14). The claims further recite that the inflammation and microbial activation results from cranial ionizing radiation, and the anti-inflammatory agent is contacted prior or subsequent to the irradiation (claims 3-5).

16. Tada et al. teach the protective effect of the anti-inflammatory agent dexamethasone on radiation induced brain damage in Japanese primates (Abstract; Discussion, para 2, 4). The results demonstrate that primates administered with dexamethasone 2 days before cranial irradiation and continued for 7 days after irradiation, display significant reduction in edema and a reduced radiation necrosis as compared to the non-dexamethasone group (Table 1, Figure 4). The data thus conclude that dexamethasone treatment before irradiation would be protective to radiation induced metabolic changes leading to neuronal cell damage and chronic inflammatory reaction (Discussion, para 4). Because the method steps disclosed by Tada et al meet the limitations of claims 1-5 and 14 of the instant application, the method described in the reference anticipates the invention.

17. Claims 1, 6, 9, 10, 13 and 14, and are rejected under 35 U.S.C. 102(b) as clearly anticipated by Ferencik et al. (Bratisl Lek Listy 102(3): 123-32, 2001).

18. The claims recite a method of protecting an individual from loss of neurogenesis resulting from inflammation and microbial activation, comprising contacting the individual with an anti-inflammatory agent or a non-steroidal anti-inflammatory agent, wherein the loss in neurogenesis capacity is reduced (claims 1, 6). The claims further recite that the loss of neurogenesis capacity is in the central nervous system, and is associated with a disease, e.g. Alzheimer's Disease, dementia, etc. (claims 9, 10, 13, 14).

19. Ferencik et al. teach that long-term administration of non-steroidal anti-inflammatory drugs (NSAID) in subjects with Alzheimer's Disease (AD) and senile dementia, result in a protective effect on the onset of AD and slows down the progression of the disease (abstract; page 128, col 2, para 1; page 129, col 1, paras 2-4). It is a well-established fact that neurodegenerative diseases like AD and dementia are associated with progressive loss of neurogenesis in the central nervous system (page 129, "Evidence of damage in neurons inflicted by infalmmatory process in AD"). Because the method steps disclosed by Ferencik et al, meet the limitations of claims 1, 6, 9, 10, 13 and 14, of the instant application, the method described in the reference anticipates the invention.

20. Claim 1, 6, 9, 10, 13 and 14, are rejected under 35 U.S.C. 102(b) as clearly anticipated by Rogers et al. (Neurology 43: 1609-1611, 1993 – included in 1449).

21. Rogers et al. teach a clinical double-blind study, wherein the NSAID indomethacin was administered to AD patients (abstract, Methods). Rogers et al. further demonstrate that indomethacin produced a protective effect on the cognitive decline in mild to moderately impaired AD patients, as compared to placebo control (Table; page 1610, col 2, para 2). It is a well-established fact that neurodegenerative diseases like AD and dementia are associated with progressive loss of neurogenesis in the central nervous system, leading to cognitive impairment. Hence the invention is anticipated by the teachings of Rogers et al.

22. Claims 1, 6, 9, 10, 13, 14 and 15, are rejected under 35 U.S.C. 102(e) as clearly anticipated by Hensley et al. (US Patent Application Publication No, 20040014721, filed on 5 June 2003).

23. The claims recite a method of protecting an individual from loss of neurogenesis resulting from inflammation and microbial activation, comprising contacting the individual with a non-steroidal anti-inflammatory agent, wherein the loss in neurogenesis capacity is reduced (claims 1, 6). The claims further recite that the loss of neurogenesis capacity is in the central nervous system or the peripheral nervous system, and is associated with a disease (claims 9, 10, 13, 14, 15).

24. Hensley et al. teach the use of anti-inflammatory compound bis(polyhydroxyphenyl), alone or in combination with NSAIDs (such as indomethacin), when administered to an individual, slows the progression of neurological diseases resulting from neuroinflammation by the stimulation of microglial cells (abstract; para 0016, 0104), thereby inhibiting the microglial activation (Table III). The anti-inflammatory compounds can be used for various neurological disorders, of the central nervous system (AD, Huntington's Disease, etc.), as well as for diseases of the peripheral nervous system (retinal degeneration) (para 0088). Because the method steps disclosed by Hensley et al, meet the limitations of claims 1, 6, 9, 10, 13, 14 and 15, of the instant application, the method described in the reference anticipates the invention.

25. Claims 1, 6, 9, 10, 13, 14, are rejected under 35 U.S.C. 102(e) as clearly anticipated by Mayer et al. (US Patent No. 6,602,881, filed on 13 May 2002, with a prior filing date of 24 March 2000, US Patent application No. 09/535,291, Mayer et al).

26. Mayer et al. teach the use of the anti-inflammatory compound manzamine, alone or in combination with NSAIDs (such as indomethacin) (col 4, lines 1-3, 9-15), for the prevention and control of neuroinflammatory conditions of the central nervous system involving microglia (AD, Parkinson's Disease, HIV, etc.) (col 1, lines 30-39; col 10, lines 31-36), in a subject, comprising administration of the

agent to the subject (col 9, lines 6-8). Because the method steps disclosed by Mayer et al, meet the limitations of claims 1, 6, 9, 10, 13, 14, of the instant application, the method described in the reference anticipates the invention.

Conclusion

27. No claims are allowed.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is (571) 272-9037. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:00 p.m.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov/. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AD
15 December 2007

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